



**An overview of ISS Human Research
Data Sharing**

by

ISSMP



Flight Data Sharing: An Overview

HRP/ISSMP

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- This presentation is an attempt to clarify several aspects of the current procedures, tools, and challenges of human data sharing for ISS flight activities.
- There are several binary variables to consider with respect to human spaceflight data sharing:
 - Medical vs. Research
 - Active Flight vs. Non-Flight
 - Tactical vs. Supplemental
 - Prospective vs. Retrospective
- This presentation will address each of these variables and how they determine which processes and mechanisms are used both to document and facilitate human data sharing
- Some of these variables will likely be so obvious that they induce eye rolls. Please bear with us. We're trying to make these slides fairly rudimentary for a wide, (eventually) international audience.
- Other distinctions are made if data originated from a NASA vs. IP crewmember. Those distinctions will be made apparent when needed



- **There are two types of human data collected for ISS:**
 - **Medical:**
 - Data collected according to MEDB or other medical requirements.
 - Data from tests for which crewmembers are required to participate.
 - To share this data you'll likely need the permission of a medical authority as well as the crewmember.
 - **Research:**
 - Data collected from the performance of a flight research study in which a crewmember's participation is voluntary.
 - To share this data you may need the permission of a PI or Project Scientist as well as the crewmember
- The focus of this presentation concerns research data sharing except where otherwise noted.



- **There are two categories of research studies:**
 - **Non-flight:**
 - Flight Analogue studies collecting data from fake astronauts
 - Data Mining Studies specifically designed to analyze previously collected data (some from astronauts).
 - Some people call these retrospective studies. And we don't disagree, but we save that retro label for something else.
 - **Flight:**
 - Research study designed specifically to collect new human data from ISS astronauts before, during, or after flight.
- This presentation focuses on Flight data. The procedures and mechanisms used to document and facilitate Flight data sharing may eventually be used to facilitate Non-flight studies.
- The most critical and current backlog is for Flight data.



- **There are two types of data sharing in which ISS human research Flight experiments engage:**
 - **Tactical:** data shared specifically to prevent redundant testing between or among 2 or more activities.
 - Data to be shared tactically is also defined as that which, if not collected, would result in an investigator not being able to answer his or her hypothesis.
 - Typically this is defined as the data set proposed for an experiment when selected for flight.
 - **Supplemental:** data sharing between investigators for the purpose of enhancing data analysis, but the failure of which would not result in the inability of an investigator to answer his or her hypothesis.
 - **Tactical & Supplemental data sharing requests are documented similarly when prospectively requested**



- **Tactical and Supplemental flight data sharing may be further divided into two more categories, defined primarily by the timeframe in which the request is made.**
 - **Prospective:** The plan to share data that has not yet been collected
 - Tactical requests are always made prospectively
 - **Retrospective:** The plan to share data that has already been collected
 - Supplemental requests may be made pro or retrospectively
- Prospective and Retrospective flight experiment data sharing differ in how they are documented and facilitated.
- Now that we've defined our binary variables, we can examine how we coordinate flight research data sharing



- **Now let's talk about how we coordinate data sharing.**
- **There are two major components:**
 - **Documentation:**
 - The process by which we document data to be shared and secure the permission needed to share it.
 - **Facilitation:**
 - Transfer of data to the parties identified in a data sharing document.
- ISSMP is involved to some degree in both of these phases for active flight studies on ISS.
- Tactical & Supplemental are treated differently in both of those phases.
 - Differences are more significant for supplemental retrospective data requests.



Documentation of Tactical Data Sharing:

- **Tactical Data Sharing is Increment (crewmember) specific, and an ISSMP generated Data Sharing Plan (DSP) is created for each mission.**
 - DSP is generated when crew science complements are finalized at ~L-9 months.
 - Main body of DSP lists all data being shared tactically among human research and MEDB testing for a given crewmember.
 - Document inputs are derived from ISSMP Experiment Documents (or Mini-EDs for International Partner experiments)
 - Document is signed by all PIs, crew surgeon, crewmembers and is the basis for tactical data sharing facilitated by ISSMP during the mission.



Documentation of Supplemental Data Sharing:

- **An investigator who wishes to engage in supplemental data sharing with another investigator must complete a Data Sharing Agreement (a template created by MHRPE and based on the ISSMP DSP template)**
 - A DSA can be created any time during the active life cycle of a flight experiment.
 - The development of a DSA is the primary responsibility of the investigator requesting the data.
 - Because this data is not critical for the completion of the study, ISSMP may not expend extra effort to help PIs develop DSAs.



Documentation of Supplemental Data Sharing (cont'd):

- **After a DSA is drafted and signed by both data requestor and provider, as well as any Sponsor (like an Element or the IP equivalent) it is then considered final.**
- **A final DSA is then stored on Sharepoint (MHRPE currently) and will be appended by ISSMP to each Increment specific DSP to which it is applicable.**
 - Example: if Biochemical Profile and Functional Immune each agree to a share a specific supplemental data set whenever they share a subject, ISSMP will include that DSA in the DSP for any Increment during which a crewmember consents to both experiments.
- If two experiments finalize a DSA with one another midway through either experiment's life cycle, the data to be shared for future crewmembers will be documented and facilitated as previously described.
- But for those subject's whose missions are already complete after a DSA is finalized...



When supplemental flight data requests go retro:

- While prospective tactical data sharing is great,
- And prospective supplemental data sharing is less great but still kind of ok because we can wrap it up into each Increment's Data Sharing Plan,
- There is still retrospective supplemental flight data sharing:
- In most cases of DSA development, the DSA will be finalized after at least one mission has been completed for an experiment from which data is requested. Requests for data from missions that precede the creation of a DSA must follow the Supplemental Flight Data Sharing process
 - [An example](#)



Supplemental Flight Data Sharing Process - Documentation:

- PI submits request to either LSDA or LSAH repository, depending on the request being for research or medical data.
- ISSMP develops a Data Use Agreement, which lists all data to be shared and from which crewmembers.
 - DUA includes signature lines for all appropriate stakeholders, including PIs and crewmembers.
- Request is routed to the Evidence Based Working Group (EBWG), which evaluates the request.
- If approved, the appropriate data sharing coordinators will secure crew consent, if required, and facilitate the data transfer.
- There are currently outstanding issues related to the Data Use Agreement and signature authority for some IPs, specifically for research studies requesting medical data. The DUA is currently held up at MMOP and HRMRB.



Data Sharing Facilitation:

- While there are differences in how prospective and retrospective data sharing requests are documented, the mechanisms by which these requests are fulfilled are largely the same.
- Prospective: Any data sharing requests included in an increment specific Data Sharing Plan will be facilitated by the ISSMP data sharing coordinator as data becomes available and subject to the existing data request queue.
 - PI to PI data sharing requests will be facilitated by the LSDW based Exploration Data Sharing Tool.
 - Medical data requested by PIs
- Retrospective: Data sharing requests made through either the LSAH-Repository or the LSDA-Repository are fulfilled by Repository personnel.
 - If data has not yet been archived requests are fulfilled as described above for prospective requests.



A further note on International Partner differences:

- There are current differences in some aspects of data sharing documentation and facilitation for data derived from IP crewmembers and data collected by IP experiments. Some examples are listed below:
 - Documentation:
 - Because only NASA maintains medical and research data repositories, any retrospective data requests for IP crewmember medical data or IP research data must be made unsystematically through those agencies.
 - Currently nobody actually wants IP research data.
 - Requests for IP medical data can currently be made through the LSAH-Repository.
 - Facilitation:
 - ESA no longer collects medical data with NASA support and maintains its data within Europe. Retrospective requests for ESA medical data require ad hoc coordination as no repository exists.
 - ESA research data is not currently archived and any requests must be coordinated directly between PIs (although they can use the LSDW)
 - MHRPE is working with IPs on the concept of an International Data Coordinator for each agency to help facilitate data exchange.



Key Points:

- Almost any supplemental data PIs want to share with other PIs, local or international, will require a Data Sharing Agreement
- PIs have the primary responsibility to develop DSAs among one another.
- PIs should be encouraged to pursue DSAs as early as possible to lower the wholesale burden on the data management community (which is largely driven by HRP dollars).
 - The retrospective aspects of data sharing coordination are more labor intensive than the prospective aspects.
- Any data to be collected via sharing must be listed in the LSRP and approved at the IRB.
- The creation of a DSA alone is not enough to begin sharing data.
- Securing the *permissions* for data sharing is a greater challenge than facilitating the *transmission* of that data.



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Backup visual aids.



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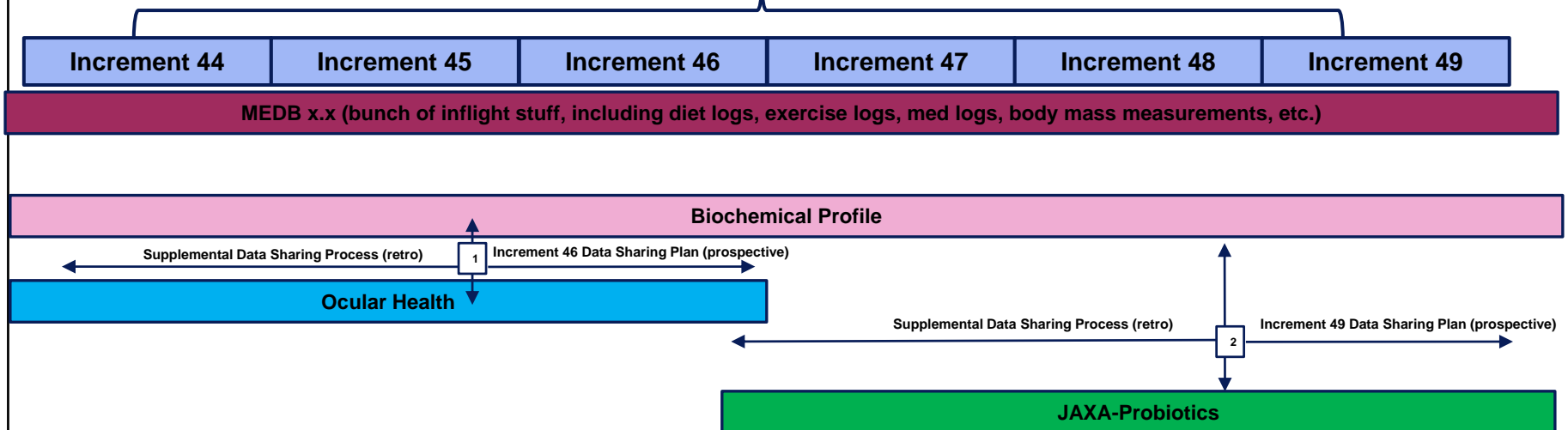
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This is a tool to help understand different flight data sharing scenarios:

NASA PI to NASA PI vs. JAXA PI to NASA PI

An uninspiring visual representation of ISS over the course of several Increments



- Two types of supplemental requests
- Each have a prospective and retro component.

1. NASA-NASA
2. NASA-JAXA.

Both are treated the same

Scenario 1:

- Ocular Health establishes DSA w/ Biochem during Inc. 45.
- Biochem agrees to share 1C data for joint subjects.
- Data sharing for Inc. 46 crew is documented in Inc 46 DSP.
- Data sharing for Increment 45 and earlier is documented via Supplemental Data Sharing Process.
- Retro data is shared via LSDA-Repository.
- Prospective data is shared PI-to-PI via LSDW

Scenario 2:

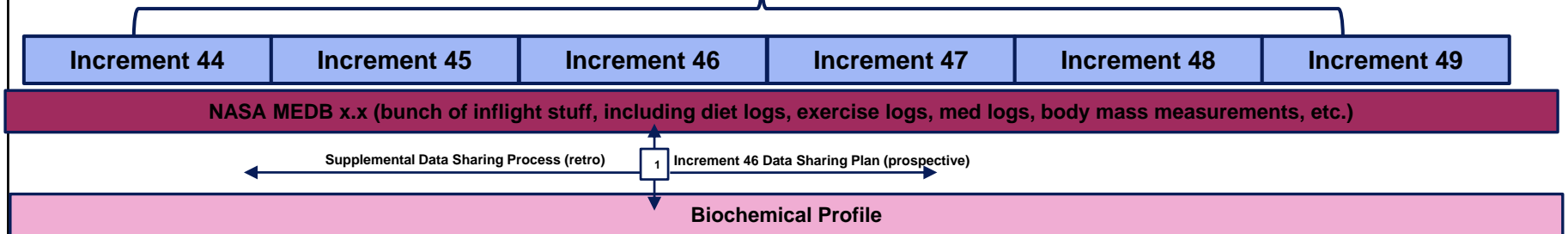
- Biochem & JAXA-Probiotics establish DSA during Inc. 48.
- JAXA agrees to share poop data w/ Biochem for joint subjects
- Data sharing for Inc. 49 crew is documented in Inc 49 DSP.
- Data sharing for Increment 48 and earlier is documented via Supplemental Data Sharing Process.
- Retro data is shared via LSDA-Repository.
- Prospective data is shared PI-to-PI via LSDW



This is a tool to help understand different flight data sharing scenarios:

NASA Medical to NASA PI

An uninspiring visual representation of ISS over the course of several Increments



NASA PI decides he needs medical data from NASA Astronaut:

Biochem Profile wants to receive medication logs from all previous and future subjects

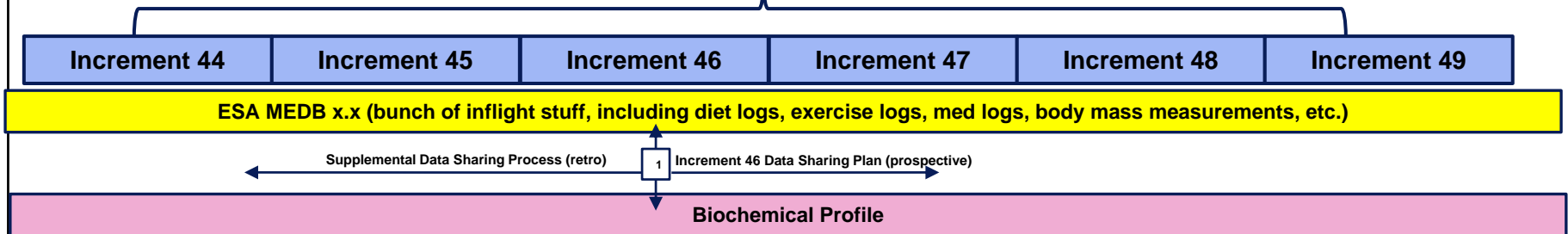
- Requests for data from astronauts Increment 46 and before are submitted via the LSAH-Repository
- Requests for data from astronauts Increment 47 and beyond will be included in the Increment specific Data Sharing Plan.



This is a tool to help understand different flight data sharing scenarios:

ESA Medical to NASA PI

An uninspiring visual representation of ISS over the course of several Increments



NASA PI decides he needs medical data from ESA Astronaut:

Biochem Profile wants to receive medication logs from all previous and future subjects (including ESA subjects)

-Requests for data from astronauts Increment 46 and before are submitted via the LSAH-Repository

The DUA requires an ESA Medical signature, which cannot be secured right now because the DUA (which is approved at JSC IRB) is still in review at HRMRB.

-Requests for data from astronauts Increment 47 and beyond will be included in the Increment specific Data Sharing Plan.

Transmission of data is coordination by ISSMP Data Sharing Coordinator in cooperation w/ ESA medical personnel



This is a tool to help understand different flight data sharing scenarios

This is the master version of this page. I just parked it here at the end of this presentation so I didn't have to keep it in a separate file. You can ignore it. But you're not because it's pretty hard to ignore something right in front of you when some guy has been talking about it for half an hour. Sorry.

An uninspiring visual representation of ISS over the course of several Increments

